

### **REMARKS**

Claims 1-3 and 5-27 are pending in the present application. Claim 1 has been amended to incorporate the subject matter of claim 4. Accordingly, claim 4 has been cancelled. Claim 2 has been amended to correct a typographical error. Claims 28-31 have been cancelled without prejudice and Applicants reserve the right to pursue these claims in a continuation application that claims priority to the present application.

#### **The Claims Are Not Anticipated by U.S. Patent No. 4,537,593 to Alchas (“Alchas”)**

Claims 1-5 and 12 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Alchas. Applicants traverse this rejection because Alchas does not describe several limitations recited in the present claims.

Alchas does not describe a shaft having a distal end “defining a distal opening and having a longitudinal axis extending through the distal opening.” There is no distal opening in any of the needles described in Alchas. Rather, Alchas describes a closed distal end (“[a] closed distal end 30 of the cannula includes a compressed planar or flat portion 31...”) (See col. 5, lines 41-45). The cannula described in Alchas does include an aperture 36 but it is “in a side wall thereof adjacent to closed distal end 30” (see col. 5, lines 56-57) and therefore does not have a longitudinal axis extending therethrough, as required by claim 1. Furthermore, Alchas does not describe a distal end terminating in a curvilinear distal tip as recited by claim 1. For at least these reasons, Applicants submit that Alchas does not anticipate claim 1 (and all claims that depend therefrom). As such, Applicants request withdrawal of this rejection.

#### **The Claims Are Not Anticipated by U.S. Patent No. 4,753,641 by Vaslow (“Vaslow”)**

Claims 1 and 6-10 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Vaslow. However, Vaslow does not describe a needle having a distal tip that terminates in a curvilinear distal tip, as recited by claim 1. As can be seen from the figures and the accompanying description of the figures, Vaslow describes a needle that terminates in a point that lies on the point longitudinal axis 14, which is parallel to the needle axis 18. (See col. 5,

lines 21-26). The edge 5, which meets point 4, is not depicted as being curvilinear. For at least this reason, Applicants submit that Vaslow does anticipate claim 1 and Applicants request withdrawal of this rejection.

**The Claims Are Not Anticipated by U.S. Patent No. 6,346, 099 to Altman (“Altman”)**

Claims 1, 11 and 13-16 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Altman. Applicants traverse this rejection because Altman does not describe several limitations of claim 1.

Altman does not describe a needle having a distal opening that has a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end, as recited by claim 1. There is no description of the projected area of the needle distal opening in Altman and the figures do not depict the distal opening such that it can be determined whether the projected area of the distal opening is smaller or larger than a cross-sectional area of any other portion of the needle shaft. Furthermore, Applicants submit that Altman does not describe a needle terminating in a curvilinear tip, as recited by claim 1. Rather, Altman describes a “simple straight hollow 316 LVM stainless steel needle.” (See col. 5, lines 55-56). For at least these reasons, Applicants submit Altman does not anticipate claim 1 (and all claims that depend therefrom). As such, Applicants request withdrawal of this rejection.

Claims 24-27 also stand rejected as being allegedly anticipated by Altman. Applicants traverse this rejection.

Claim 24 recites a method of directly delivering a therapeutic agent to a target site of a body by using a Huber needle. The Examiner submits that the needle 312 described by Altman is a Huber needle. However, there is no indication that needle 312 or any of the other needles described by Altman are Huber needles. As described in the present specification, Huber needles generally have a lateral bend and a laterally facing opening as illustrated in Figure 9. No such needle is illustrated or described in Altman. For at least this reason, Applicants submit that Altman does not anticipate claim 24 (and all claims that depend therefrom). As such, Applicants request withdrawal of this rejection.

**The Claims Are Not Anticipated by U.S. Patent No. 5,873,864 to Luther (“Luther”)**

Claims 1 and 17-20 stand rejected as being allegedly anticipated by Luther. Applicants traverse this rejection because Luther does not describe several limitations of claim 1.

Claim 1 recites that the shaft has a distal end defining a distal opening and having a longitudinal axis extending through the distal opening. Applicants submit that Luther does not describe this limitation. As is clearly seen in Figure 3 of Luther, the opening at the end of needle tip 48 is offset from the longitudinal axis of the catheter 26. Further, there is no description of the projected area of the needle distal opening in Altman and the figures do not necessarily illustrate the distal opening having a projected area smaller than a cross-sectional area of any other portion of the needle shaft. Moreover, Luther does not describe a needle terminating in a curvilinear tip, as recited by claim 1. For at least these reasons, Applicants submit that Luther does not anticipate claim 1 (and all claims that depend therefrom). As such, Applicants request withdrawal of this rejection.

**The Claims Are Not Anticipated by U.S. Patent No. 5,843, 048 to Gross (“Gross”)**

Claims 1 and 21 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Gross. Applicants traverse this rejection.

Similar to Luther, Gross does not describe a distal end defining a distal opening and having a longitudinal axis extending through the distal opening. The distal opening 34 of Gross is offset from the longitudinal axis of shaft 12, as seen in Figure 1. Further, there is no indication in Gross that the projected area of the distal opening is smaller than a cross-sectional area of the shaft proximal to the distal end. If anything, the projected area appears bigger than the cross-sectional area of the shaft proximal to the distal end, as seen in Figure 1. Further, Gross does not describe a needle terminating in a curvilinear tip, as recited by claim 1. For at least these reasons, Applicants submit that Gross does not anticipate claim 1 (and all claims that depend therefrom). As such, Applicants request withdrawal of this rejection.

**The Claims Are Not Anticipated by U.S. Patent No. 5,817,052 to Johnson (“Johnson”)**

Claims 1, 22, and 23 stand rejected as being allegedly anticipated by Johnson under 35 U.S.C. 102(b). Applicants traverse this rejection because Johnson does not teach several of the claim limitations of claim 1.

According to the Examiner, Johnson describes a shaft defining a distal opening 52 that has a longitudinal axis extending therethrough. However, distal opening 52 is a side port and the longitudinal axis of infusion tube 31 does not extend through distal opening 52 (See col. 14, lines 3-5). Further, Johnson does not describe a needle terminating in a curvilinear tip, as recited by claim 1. For at least these reasons, Applicants submit that Johnson does not anticipate claim 1 (and all claims that depend therefrom). As such, Applicants request withdrawal of this rejection.

**Rejection of Claims as Being Allegedly Anticipated by U.S. Patent Publication No. 2004/0101225 to Dinsmore ("Dinsmore") is Rendered Moot**


Claims 28-31 have been cancelled and therefore the rejection of these claims as being allegedly anticipated by Dinsmore is rendered moot. As such, Applicants request withdrawal of this rejection.

**CONCLUSION**

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Dated: 3/7/06

Respectfully submitted,  
KENYON & KENYON  
  
By: Zeba Ali  
(Reg. No. 51,392)

1500 K Street, N.W.  
Suite 700  
Washington, D.C. 20005  
Tel: (202) 220-4200  
Fax: (202) 220-4201